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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/075,375	05/07/1998	HARRY Y. YAMAMOTO	CGNE119-2US	3584

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MONSANTO COMPANY  
800 N. LINDBERGH BLVD.  
ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)  
ST. LOUIS, MO 63167

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/075,375

Applicant(s)

YAMAMOTO ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 and 25 is/are rejected.
- 7) ☒ Claim(s) 24 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/09/2003 has been entered.

Claims 23-26 are pending and examined.

### ***Drawings***

The drawings submitted 10/12/2001 are objected to for reasons of record set forth in the notice of draftperson's patent drawing review submitted in the office action dated 7/30/2003.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of producing a plant with a modified level of zeaxanthin by transformation with a DNA sequence encoding a plant violaxanthin de-epoxidase.

Applicants describe SEQ ID NO: 1, 3 and 5 encoding plant violaxanthin de-epoxidases from lettuce, tobacco and *Arabidopsis* of SEQ ID NO: 2, 4 and 6 respectively; a conserved domains shared between the three polypeptides of SEQ ID NO: 2, 4, and 6 in figure 4 and on pages 6 and 18-19 of the specification.

Applicants do not describe any other isolated polynucleotide sequences that encode a plant violaxanthin de-epoxidase.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of DNA sequences encoding a plant violaxanthin de-epoxidase falling within the scope of the claimed genus. Applicants only describe SEQ ID NO: 1, 3 and 5 from lettuce, tobacco and *Arabidopsis*. Further, Applicants fail to describe structural features that constitute a substantial portion of the genus, i.e. common to all members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*.

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Claims 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a lettuce, tobacco, or *Arabidopsis* plant with a reduced level of zeaxanthin by transformation with an antisense DNA of SEQ ID NO: 1, 3 or 5 and plants produced thereby does not reasonably provide enablement for a method of antisense inhibition of zeaxanthin production in all plants, or a method of producing any plant with an increased level of zeaxanthin by transformation with any DNA sequence encoding a plant violaxanthin de-epoxidase in sense orientation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicant broadly claims a method of producing a plant with a modified level of zeaxanthin by transformation with a DNA encoding a plant violaxanthin de-epoxidase (VDE).

Applicants teach an isolated DNA of SEQ ID NO: 1 encoding lettuce VDE isolated by PCR amplification using DNA primers derived from protein sequence analysis of fragments of a tryptic digest of isolated lettuce VDE enzyme (Example 1 pages 17-19), recombinant expression

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of SEQ ID NO: 1 in *E. coli* and measurement of VDE activity (examples 2-3 pages 19-22), expression of antisense tobacco VDE encoding DNA in tobacco plants resulting in no detectable levels of zeaxanthin (example 4 page 23); SEQ ID NO: 3 and 5 encoding plant violaxanthin de-epoxidase enzymes from tobacco and *Arabidopsis* (see sequence listing); and tobacco plants transformed with a lettuce VDE sense construct having a delay in senescence and larger flowers, wherein the levels of zeaxanthin were uncharacterized (example 4, page 23).

Applicant does not teach modified zeaxanthin levels in any plant other than reduced zeaxanthin levels in tobacco

The degree of unpredictability when attempting to modify the physiological trait of a plant by means of an antisense construct is directly related to the degree of sequence relatedness among gene family members as well as the degree of relatedness across a broad range of species when a high degree of sequence identity is required and a limited number of isolated cDNA clones do not cover the entire gamut of plant species with respect to their sequence identity and will not enable a broadly claimed antisense strategy. The reference teaches that an antisense chalcone synthase construct from *Phaseolis vulgaris* was used to transform *Lotus corniculatus* resulted in an increase rather than a decrease in endogenous CHS levels the heterologous CHS antisense construct yielded an increase in the level of detectable CHS transcripts when compared to the control plants. (Colliver S.P. *et al.* Plant Mol. Biol. 1997; Vol. 35, pp. 509-522; see page 517, column 2 to page 518 column 1). Further, the authors also remark that in polyploid plant species the allelic variation due to outbreeding can result in a heterogeneous gene family having a range of susceptibility to antisense suppression (page 519, column 1 lines 8-16). Furthermore, Applicant's transformation of tobacco with the lettuce VDE sense construct did not result in

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plants with modified levels of zeaxanthin and thus, further demonstrates the unpredictability in attempting to modify zeaxanthin levels in plants using heterologous constructs.

Based upon Applicant's limited guidance one cannot predict which embodiments would be operable and thus undue trial and error experimentation would be required by one of skill in the art to isolate and test the multitude of non-exemplified DNA sequences that fall within the claimed genus of DNA sequence that encode plant violaxanthin de-epoxidases or screen a myriad of non-exemplified transformed plants from any species for modified levels of zeaxanthin encompassed by the claims.

Given the unpredictability in the art as to which polynucleotide sequences encode a plant violaxanthin de-epoxidase; the breadth of the claims encompassing any polynucleotide sequence encoding a plant violaxanthin de-epoxidase; the lack of guidance in the examples of the specification or in the prior art as to which nucleotide sequences encoding plant violaxanthin de-epoxidases would modify zeaxanthin levels; and the undue trial and error experimentation required to practice the claimed invention, the invention is not enabled for the scope set forth in the claims.

Claims 23 and 25 are rejected

Claims 24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claims are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method of modifying zeaxanthin levels in plants by transformation with a DNA encoding a plant violaxanthin de-epoxidase.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
May 25, 2004



**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**